PART F

USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS

Sec. F.1 Purpose and Scope. This Part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment by, or under the supervision of, an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Parts A, B, D, J and K of the regulations. Some registrants may also be subject to the requirements of Parts I and X of the regulations.

Sec. F.2 Definitions. As used in this Part, the following definitions apply:

“Absorbed dose (D)” means the energy deposited by ionizing radiation per unit mass (of any material). The conventional unit of absorbed dose is the rad. One rad is equal to 0.01 J/kg. The International Standard (SI) unit of absorbed dose is the gray (Gy) (1 Gy = 100 rad).

"Accessible surface diagnostic" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Added filtration diagnostic" means any filtration which is in addition to the inherent filtration.

“Air Kerma” means the kinetic energy released by ionizing radiation per unit mass of air. This unit is the gray. The air kerma in gray (mGy) is equivalent to exposure in roentgen (R) multiplied by 8.37 E+2.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

"Barrier" (See "Protective barrier").

"Beam axis diagnostic" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device (collimator)” means a device to restrict the dimensions of the x-ray field.

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1 The nominal chemical composition of type 100 aluminum is 99.00 percent minimum aluminum, 0.12 percent copper.

2 See Footnote #1.

"C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, the Food and Drug Administration.

"Certified system" means any x-ray system which has one or more certified component(s).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

“C” or “Coulomb” means the SI unit of electric charge.

"Cv” or “Coefficient of variation” means the ratio of the standard deviation to the mean value of a set of observations. It is estimated using the following equation:

$$Cv = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

$\bar{x}$ = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations in sample.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

“Collective Dose” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

“Collimator” see Beam Limiting Device.

"Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{nT}\int_{-7T}^{+7T} D(z)dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

“CT” or "Computed tomography" means the production of a cross-sectional image through acquisition and computer processing of a tomogram.

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in F.2.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT Number" means the number used to represent the x-ray attenuation associated with each pixel of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (See "Radiations detector").

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

“Dose equivalent” (see Equivalent dose).

“Dose limits” means the upper bounds of radiation doses established in accordance with the regulations. For purposes of the regulations, “limits” is an equivalent term.

“Dose profile diagnostic” means dose as a function of position in any direction perpendicular to the beam axis.

"Dose profile CT" means the dose as a function of position along a line.

“Effective equivalent dose (H_E)” means the sum of the products of the equivalent dose (H) for each organ or tissue and the tissue weighting factor (w_T): $H_E = \sum_T w_T \times H\,(\mathrm{Sv})$. The unit of effective equivalent dose is the Sievert. See Appendix (C) for a table on tissue weighting factors.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment").

“Equivalent dose (H_T)” means the product of absorbed dose (D) and the radiation weighting factor (W_R), formerly called the quality factor (Q): $H_T = W_R \bullet D$. The unit of equivalent dose is the Sievert (Sv). See Appendix (C) for a table of radiation weighting factors (W_R).

“Exposure rate” means exposure per unit time (R/s) as measured at the center of the useful beam.

“Extremity” means hand, elbow, arm below the elbow, foot, knee and leg below the knee.

“Eye equivalent dose” means the equivalent dose (H) received by the eye at a tissue depth of 0.3 cm.

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter diagnostic" means material placed in the useful beam to preferentially absorb selected radiations.

"Fluoroscopic imaging assembly" means a subsystem by means of which a radiographic image is produced in real time. The assembly includes an image receptor, such as an image intensifier and an image display such as a CRT and/or a spot film device.

"Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates. The actual dimensions of the focal spot can be measured by means of a pinhole camera.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"HVL diagnostic or Half-value layer diagnostic" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced by one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

Houndsfield – (see CT number).

"Image intensifier" means a device which converts the image information carried by an x-ray beam (the x-ray attenuation pattern) into a visible light image which can be observed in real time; i.e., during the course of the exposure.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the x-ray tube and the tube housing.

“Interventional fluoroscopy x-ray system” means an x-ray system in which the beam axis of the x-ray beam is not constrained to be perpendicular to the plane of the x-ray tube.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation diagnostic" means radiation emanating from the diagnostic source assembly except for:

(1) the useful beam; and

(2) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential;

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where:

V_n = No-load line potential;
V_l = Load line potential.

“lx” or “Lux” means a characteristic of a radiation receptor.

"mA" means milliampere.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

“Medical Institution” means an organization in which several medical disciplines are practiced.

"Mobile x-ray equipment" (See "X-ray equipment").

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \bullet \mu_x \bullet s}{\mu_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Patient diagnostic" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" or "Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom diagnostic" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Picture element or pixel” means a two-dimensional element of a projection image, usually represented by a single numerical value called the pixel value.

"PID" or "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Portable x-ray equipment" (See "X-ray equipment").

"Primary protective barrier" (See "Protective barrier").

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam;

(2) "Secondary protective barrier" means the material which attenuates stray radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“Radiation weighting factor (W_R)” means a weighting factor used in calculating equivalent dose, which takes account of the relative effectiveness of the particular kind of ionizing radiation in producing biological damage. The radiation weighting factor (W_R) was formerly called the quality factor (Q). (See Appendix (C) for a table of radiation weighting factors.)

"Radiograph" means a displayed image of an x-ray attenuation pattern, e.g., on photographic film or on a CRT display.

"Radiographic imaging system" means any system that permanently or semi-permanently records a radiographic image on an image receptor and displays the recorded image as a radiograph.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means creation of a retrievable, permanent or semi-permanent record of a radiographic image.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

“Roentgen” means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Scattered radiation" means radiation emitted by interaction with matter, the interaction being accompanied by a change in direction of the radiation. (See "Direct scattered radiation").

"Secondary protective barrier" (See "Protective barrier").

“Sensitometer” means a device for exposing photographic x-ray film to visible light of varying intensity.

“Sensitometric test” means determination of the response curve of a photographic film. The response curve shows the dependence of film optical density (OD) plotted on the ordinate (y-axis) to exposure, plotted as the logarithm of exposure (log E) on the abscissa (x-axis). The exposure scale may be relative or absolute. This test may be performed by exposing the film to visible light from a calibrated sensitometer or by exposing the film/intensifying screen system to x-rays.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

“SID” or "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

"Source diagnostic" means the focal spot of the x-ray tube.

“Spot check” means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD diagnostic or Source-skin distance diagnostic" means the distance between the source and the skin entrance plane of the patient.

"Stationary x-ray equipment" (See "X-ray equipment").

“Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a function of dose without threshhold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of the regulations, “probabilistic effect” is an equivalent term.

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

(3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“Tissue weighting factor (W_T)” means a weighting factor used in calculating effective dose intended to assign the proportion of risk of stochastic effects resulting from irradiation of a particular tissue compared to uniform whole body irradiation. (See Appendix (C) for a table of tissue weighting factors.)

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

“Weighting factor” (see Radiation Weighting Factor or Tissue Weighting Factor).

“Whole body” means, for purposes of exposure, head, trunk including gonads, arms above the elbow, or legs above the knee.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

"X-ray tube diagnostic" means any electron tube which is designed for the conversion of electrical energy into X-ray energy.

Sec. F.3 General and Administrative Requirements

a. Radiation Safety Requirements. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of the regulations are met in the operation of the x-ray system(s).

i. An x-ray system which does not meet the provisions of the regulations shall not be operated for diagnostic purposes.

ii. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Appendix A for a list of subject matters pertinent to this requirement. The agency may use interview, observation and/or testing to determine compliance.

iii. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(1) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

(2) Type and size of the film or film-screen combination to be used;

(3) If a grid is used, type and focal distance.

(4) Source to image receptor distance to be used (except for dental intra-oral radiography);

iv. The registrant of a facility shall create and make available to x-ray operators written safety procedures including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these ~~rules~~ procedures.

v. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

(2) The x-ray operator, other staff, and ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

(3) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

vi. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

vii. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by F.3a.

viii. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by F.3a.iv., shall list individual projections where holding devices cannot be utilized;

(2) Written safety procedures, as required by F.3a.iv., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(3) The human holder shall be instructed in personal radiation safety and protected as required by F.3a.v.;

(4) No individual shall be used routinely to hold film or patients;

(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(6). Each facility shall have leaded aprons and gloves if needed available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

ix. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(1) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic

radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

(2) The exposure to the patient shall be the minimum exposure required to produce images of a quality adequate to the diagnostic task. Patient exposure is commonly called the entrance skin exposure (ESE).

(3) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary ~~x-ray~~ radiographic installation.

(4) X-ray systems subject to F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems and except in dental cases specified in Section F.7.

(5) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

(b) If of the focused type, be of the proper focal distance for the SIDs being used.

x. All individuals who are associated with the operation of an x-ray system are subject to the requirements regarding occupational dose limits, prior occupational dose, occupational dose limits for minors and dose to an embryo/fetus of D.201, D.205, D.207 and D.208 of the regulations.

xi. Healing Arts Screening. Any person proposing to conduct a radiation screening shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of this Part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

xii. Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

(1) Model and serial numbers of all major components, and user's manuals for those components;

(2) Tube rating charts and cooling curves;

(3) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and

(4) A copy of all correspondence with this Agency regarding that x-ray system for at least two (2) consecutive inspection cycles providing there are no violations. This includes application forms, registrations, and inspection forms. However, the Certificate of Approval (Form R15) shall be kept indefinitely.

xiii. X-Ray Utilization Record. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed.

xiv. Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Agency (generally amended to the product manual):

(1) maximum rating of technique factors;

(2) model and serial numbers of all certifiable components;

(3) aluminum equivalent filtration of the useful beam, including any routine variation;

(4) tube rating charts and cooling curves;

(5) records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) with the names of persons who performed such services;

xv. A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

(1) the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or

(2) the type and thickness of materials, or lead equivalency, of each protective barrier; and

xvi. A copy of all correspondence with this Agency regarding that x-ray system.

xvii. Written Policy. Each facility shall have a written policy for evaluating the exposure to individuals in instances where the examination is not specified in the technique chart required in F.3(a) or where the patient or film is supported by a human holder as specified in F.3.a.

b. Plan Review

i. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Agency for review and approval. The required information is denoted in Section B.4 of the regulations. Information regarding these requirements shall be provided to anyone requesting it for the purpose of using x-ray equipment in medical, dental, veterinary and industry applications.

ii. The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

c. X-Ray Film Processing Facilities and Practices.

i. Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film:

(a) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(b) Film shall be developed in accordance with the manufacturer's instructions and with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations with the following time-temperature chart:

ATTACHMENT 1

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
^{o}C	^{o}F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

(c) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems:

(a) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

ATTACHMENT 2

Developer Temperature		Minimum Immersion Time[a/]
^{o}C	^{o}F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] *Immersion time only, no crossover time included.*		

(b) The specified developer shall be posted in the darkroom or on the automatic processor.

(3) Processing deviations from the requirements of F.3.c.i. shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

ii. Other Requirements.

(1) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(2) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

(3) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(4) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(5) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

(6) Outdated x-ray film shall not be used for radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal performance (base + fog, speed, contrast) per the manufacturer's specifications.

(7) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

Sec. F.4 General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

a. Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (2 milliroentgens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of ~~100~~ 200 square centimeters with no linear dimension greater than 10 centimeters.

e. Beam Quality.

i. Half-Value Layer.

(1) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I				
X-Ray Tube Voltage (Kilovolt Peak)		Minimum HVL (Millimeters of Aluminum)		
Designed Operating Range	Measured Operating Potential	Dental Intra-Oral Manufactured Before Aug. 1. 1974 and On or After Dec. 1, 1980	Other X-Ray Systems Except Interventional Fluoroscopy Systems	Interventional Fluoroscopy X-Ray Systems
Below 51	30	1.5	0.3	
	40	1.5	0.4	1.5
	50	1.5	0.5	1.8
51 to 70	51	1.5	1.2	
	60	1.5	1.3	2.5
	70	1.5	1.5	2.5
	71	2.1	2.1	
Above 70	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	-
	140	3.8	3.8	-
	150	4.1	4.1	-

(2) For capacitor energy storage equipment, compliance with the requirements of F.4.e.i. shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

(3) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

ii. Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by F.4e.i. is in the useful beam for the given kVp which has been selected.

f. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

h. Technique Indicators.

i. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

ii. The requirement of F.4.h.i. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

i. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

j. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

Sec. F.5 Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:

a. Limitation of Useful Beam.

i. Primary Barrier.

(1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(2) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

ii. Fluoroscopic Beam Limitation - Aperture size shall be specified in terms of Geometric Efficiency = Visible Area (cm^2) • 100/X-ray field (cm^2), and with a minimum geometric efficiency of 80% should be imposed at any SID. For receptors having a diameter greater than 34 cm, the x-ray field measured along a diameter in the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the visible area of the image receptor by more than 2 cm.

(1) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 per-cent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(2) Other requirements for fluoroscopic beam limitation:

(a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

(b) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

(d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(e) For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

iii. Spot-film Beam Limitation. Spot-film devices shall meet the following requirements:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

(3) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

(4) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

(5) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

iv. Override. If a means exists to override any of the automatic x-ray field size adjustments required in F.5a.ii. and iii., that means:

(1) Shall be designed for use only in the event of system failure;

(2) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(3) Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

b. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure Rate Limits

i. Entrance Exposure Rate Allowable Limits.

(1) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) Compliance with the requirements of F.5c. shall be determined as follows:

(a) If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle;

(b) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(c) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(4) Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:[3]

(a) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;

(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in F.3.a.xii.(3). The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the ~~person~~ individual performing the measurements and the date the measurements were performed shall be included in the results;

(c) Conditions of periodic measurement of typical entrance exposure rate are as follows:

(d) The measurement shall be made under the conditions that satisfy the requirements of F.5c.i.(3);

(e) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

(f) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of F.5c.ii.(3)(b);

(g) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

3 Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.

(1) The measurement shall be made under the conditions that satisfy the requirements of F.5c.i.(3);

(2) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

(3) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attentuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

d. Barrier Transmitted Radiation Rate Limits.

i. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate.

ii. Measuring Compliance of Barrier Transmission.

(1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(3) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(4) Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-Skin Distance. The SSD shall not be less than:

i. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

ii. 35.5 centimeters on stationary fluoroscopic manufactured prior to August 1, 1974;

iii. 30 centimeters on all mobile fluoroscopes; or

iv. 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

g. Fluoroscopic Timer.

i. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

ii. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

h. Control of Scattered Radiation.

i. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

ii. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(1) Is at least 120 centimeters from the center of the useful beam; or

(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in F.3a.v.

iii. The Agency may grant exemptions to F.5h.ii. where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. Other than those that are exempt in Appendix B, approval will be granted automatically if the procedure is approved in writing by the Radiation Safety Officer.

i. Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of F.6d. when operating in the spot film mode.

j. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of F.5c. In addition, these systems shall be exempt from:

i. The requirements of F.5.a. and F.5d. provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

ii. The requirements of F.5g. if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. A maximum absorbed dose of one (1) gray (100 rads) or more delivered to a patient shall be reported to the Agency per Sec. D.1203.

Sec. F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography X-Ray Systems.

a. Beam Limitation, Except Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of F.6h.ii. has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

i. General Purpose Stationary and Mobile X-Ray Systems, Including Veterinary Systems (Other than Portable) Installed After the Effective Date of The Regulations.

(1) Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

(2) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(3) No uncertified system shall be installed after the issuance date of the regulations.

(a) Demonstrates it is impractical to comply with F.6a.i.(1) and (2); and

(b) The purpose of F.6a.i.(1) and (2) will be met by other methods.

ii. Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.6a.i., stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(1) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and

(3) Indication of field size dimensions and SIDs shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

iii. X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

iv. X-Ray Systems Other Than Those Described in F.6a.i., ii., and iii., and Veterinary Systems Installed Prior to the Effective Date of The Regulations and all Portable Veterinary X-Ray Systems.

(1) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(2) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(3) F.6.a.iv.(1) and (2) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6~~(a)(1)~~a.i. or, when alignment means are also provided, may be met with either:

(a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation Exposure Control

i. Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

ii. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

iii. Exposure Termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(1) Manual Exposure Control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(a) Exposure of ½ second or less; or

(b) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(2) Automatic Exposure Controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

(c) The minimum exposure time for all equipment other than that specified in F.6b.ii.(2)(b) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

(d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 400 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 1000 mAs per exposure; and

(d) A visible signal shall indicate when an exposure has been terminated at the limits required by F.6.b.ii.(2)(d), and manual resetting shall be required before further automatically timed exposures can be made.

iv. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

v. Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

vi. Operator Protection, Except Veterinary Systems.

(1) Stationary Systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(2) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

(a) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.6b.vi.(1);

(b) Used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

vii. Operator Protection for Veterinary Systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

d. Exposure Reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

i. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

ii. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

iii. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

h. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

i. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

(1) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

(2) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

(3) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the

light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

ii. Beam Limitation and Alignment on Stationary General Purpose X-Ray Systems Equipped with PBL. If PBL is being used, the following requirements shall be met:

(1) PBL shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.6h.ii.(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(b) The sum of the length and width differences as stated in F.6h.ii.(1)(a) without regard to sign exceeds 4 percent of the SID;

(2) Compliance with F.6h.ii.(1) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

(3) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

(4) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in F.6h.ii.(1), then any change of image receptor size or SID must cause the automatic return.

iii. Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of F.6a.i. or F.6h.ii.

i. Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

Sec. F.7 - Intraoral Dental Radiographic Systems. In addition to the provisions of F.3 and F.4, the requirements of F.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.6. Only systems meeting the requirements of F.7 shall be used.

a. Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:

i. 18 centimeters if operable above 50 kVp; or

ii. 10 centimeters if operable at 50 kVp only.

b. Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be

containable in a circle having a diameter of no more than 7 centimeters and no more than 10 centimeters for occlusal x-rays.

c. Radiation Exposure Control.

i. Exposure Initiation.

(1) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(2) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

ii. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

iii. Exposure Termination.

(1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(2) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of ½ second or less.

(3) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

iv. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values.

v. Exposure Control Location and Operator Protection.

(1) Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the x-ray activation switch shall be so placed that the operator can view the patient while making any exposure.

(2) Mobile and portable x-ray systems which are:

(a) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of F.7c.v.(1);

(b) Used for less than one week in the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly while making exposures.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

i. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1+X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

ii. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 +X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

iii. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 5 percent of the indicated value for kVp and 10 percent for time.

g. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative Controls.

i. Patient and film holding devices shall be used when the techniques permit.

ii. The tube housing and the PID shall not be hand-held during an exposure.

iii. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.7b.

iv. Dental fluoroscopy without image intensification shall not be used.

Sec. F.11 Computed Tomography X-Ray Systems.

a. Requirements for Equipment.

i. Termination of Exposure.

(1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subdivision F.11b.i.(1).

(3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

ii. Tomographic Plane Indication and Alignment.

(1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(3) If a device using a light source is used to satisfy the requirements of Subdivisions F.11b.ii.(1) or (2), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

iii. Beam-On and Shutter Status Indicators and Control Switches.

(1) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(2) Each emergency button or switch shall be clearly labeled as to its function.

iv. Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

v. Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by F.4c.

vi. Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

vii. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(4) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

b. Facility Design Requirements.

i. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

ii. Viewing Systems.

(1) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(2) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

c. Surveys, Calibrations, Spot Checks, and Operating Procedures.

i. Surveys.

(1) All CT x-ray systems installed after July 10, 2002, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report from the qualified expert and that qualified expert shall be registered with the Agency, and a copy of the report shall be made available to the Agency upon request.

ii. Radiation Calibrations.

(1) The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

(2) The calibration of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

(3) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(4) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(b) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(c) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

(d) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(5) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(6) Calibration shall meet the following requirements:

(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(b) The CTDI[4] along the two axes specified in Subdivision F.11d.ii.(4)(b) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;

(c) The spot checks specified in F.11d.iii. shall be made.

(7) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

iii. Spot Checks.

(1) The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

(2) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(3) All spot checks shall be included in the calibration required by F.11d.ii. and at time intervals and under system conditions specified by a qualified expert.

(4) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by F.11d.ii. The images shall be retained, until a new calibration is performed, in two forms as follows:

(a) Photographic copies of the images obtained from the image display device; and

4 For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

(b) Images stored in digital form on a storage medium compatible with the CT x-ray system.

(5) Written records of the spot checks performed shall be maintained for inspection by the Agency.

iv. Operating Procedures.

(1) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(2) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(b) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(c) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(d) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

Sec. F.12 - Mammography. See FDA Requirements as specified in [21 CFR 900.]

PART F

APPENDIX A

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT RADIATION SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;

b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;

c. A detailed description of the x-ray examinations proposed in the screening program;

d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;

e. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-x-ray examinations;

f. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of the regulations. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;

g. A description of the diagnostic x-ray quality control program;

h. A copy of the technique chart for the x-ray examination procedures to be used;

i. The qualifications of each individual who will be operating the x-ray system(s);

j. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;

k. The name and address of the individual who will interpret the radiograph(s);

l. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;

n. An indication of the frequency of screening and the duration of the entire screening program.

PART F

APPENDIX B

EXEMPTIONS FROM SHIELDING FOR CERTAIN FLUOROSCOPIC PROCEDURES

a. Angiograms

b. Arthrograms

c. Biliary drainage procedures

d. Fluoroscopic biopsy procedures

e. Myelograms

f. Percutaneous cholangiograms

g. Percutaneous nephrostomies

h. Sinograms or fistulograms

i. T-tube cholangiograms

PART F

APPENDIX C

Tissue Weighting Factors (w_T) Assigned by the International Commission on Radiological Protection*

Tissue/Organ	w_T
Gonads	0.20
Stomach	0.12
Colon	0.12
Lung	0.12 (0.08) I
Red bone marrow	0.12
Breast	0.05
Esophagus	0.05
Bladder	0.05
Liver	0.05
Thyroid	0.05
Bone surfaces	0.01
Skin	0.01H
Remainder	0.05

* Adapted from 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 60, Oxford: Pergammon 1991.
H Applied to the mean equivalent dose over the entire skin.
I Bronchial epithelium

Radiation Weighting Factors (w_R) for Various Types of Radiation*

Type of Radiation	Radiation Weighting Factor (w_R)
X-rays, gamma rays, beta particles and electrons[H]	1
Protons (>2 MeV)	5
Neutrons (energy dependent)	5-20
Alpha particles and other charged particles	20

* For radiations principally used in medical imaging (x-rays, gamma rays, beta particles) $w_R = 1$; thus the absorbed dose and equivalent dose are equal (i.e. 1 Gy = 1 Sv). Adapted from 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 60, Oxford: Pergammon 1991.

H $w_R = 1$ for electrons of all energies except for Auger electrons emitted from nuclei bound to DNA.